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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/405,454	03/15/95	SULLIVAN J	4249.0002-05

EXAMINER	
SCHWADRON, R.	
ART UNIT	**PAPER NUMBER**
1644	33

HM11/0414

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DATE MAILED: 04/14/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/19/97

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 40-42, 45-47 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 40-42, 45-47 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

15. Claims 40-42,45-47 are under consideration. Claims 40 and 45 have been amended. Claims 43,44,48,49 have been cancelled.

RESPONSE TO APPLICANTS ARGUMENTS

16. Claims 40-42 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in paragraph 17 of the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the recitation of "antivenom" in claim 40. The specification and original claims read on antivenin not antivenom.

Regarding applicants comments about the Russell declaration filed 12/19/97, said declaration was filed in unsigned form (eg. not signed by Russell). The Russell declaration will be fully considered upon receipt of a signed copy of said declaration. However, Russell (J. Of Toxicol., 1988) filed with the aforementioned declaration indicates on pages 75-76 (see antivenin) that while the term antivenin is restricted to an immunoglobulin based preparation that the term antivenom is not so restricted (eg. it encompasses non immunoglobulin ingredients). Thus, it appears the two terms are actually not interchangeable.

17. Claims 40-42,45-47 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in paragraph 18 of the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the recitation of "essentially free from contaminating Fc" in claims 40 and 45. The specification and original claims 27 and 29 do not recite that the claimed F(ab) are essentially free from contaminating Fc. They recite that the claimed F(ab) produce an electrophoresis wherein no precipitation band against anti-Fc antibodies is seen.

Regarding applicants comments, there is no disclosure in the specification as originally filed that the claimed F(ab) are essentially free from contaminating Fc. The specification discloses that the claimed F(ab) produce an electrophoresis wherein no precipitation band against anti-Fc antibodies is seen. There is no disclosure in the specification as originally filed of the scope of the claimed invention wherein the claimed invention is essentially free from contaminating Fc. Regarding applicants comments about the four-hour digest in Figure 4 of the specification, said preparation is not essentially free from contaminating Fc because it contains detectable levels of Fc. Furthermore, the particular experiment which applicant refers to discloses a particular preparation generated under a particular set of conditions. There is no support in the specification as originally filed of the scope of the claimed invention. There is no written description of the scope of the claimed invention in the specification as originally filed.

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 40-42,45-47 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan et al. in view of Coulter et al. and Smith et al. as evidenced by Stedman's Medical Dictionary (1977) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Applicants arguments in pages 6-10 of the instant amendment are based on the Russell declaration filed 12/19/97. Regarding the Russell declaration filed 12/19/97, said declaration was filed in unsigned form (eg. not signed by Russell). The Russell declaration will be fully considered upon receipt of a signed copy of said declaration. Applicant is correct in stating that Sullivan (1996) is not prior art as regards the claimed inventions.

20. Claims 45-47 remain rejected under 35 U.S.C. § 103 as being unpatentable over Sullivan et al. in view of Coulter et al. for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Applicants arguments in pages 6-10 of the instant amendment are based on the Russell declaration filed 12/19/97. Regarding the Russell declaration filed 12/19/97, said declaration was filed in unsigned form (eg. not signed by Russell). The Russell declaration will be fully considered upon receipt of a signed copy of said declaration. Regarding applicants arguments as they apply to the instant rejection, the claimed invention under consideration is not drawn to an antivenom. It is drawn to a Fab antibody. Whether or not an antivenom based on the Fab recited in the claims could be used to treat snake bites in vivo is not germane to the claimed invention because the claimed Fab can be used in in vitro assays. Coulter et al. teach that: "Fab fragments of IgG have been used in enzyme immunoassay instead of IgG (Kato et al. 1976). EIAs of higher sensitivity have been claimed when Fab enzyme is used instead of IgG enzyme." (page 199, first paragraph).

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

22. Claims 40-42,45-47 stand rejected under 35 U.S.C. 102(a) as being anticipated by Sullivan et al. (Veterinary and Human Toxicology) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Regarding the second Russell declaration filed 12/19/97, said declaration was filed in unsigned form. The Russell declaration will be fully considered upon receipt of a signed copy of said declaration.

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
April 13, 1998

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600